

Food and Drug Administration, HHS

Pt. 890

a patient. This generic type of device includes the electric cast cutter and cast vacuum.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §888.9.

[55 FR 48443, Nov. 20, 1990, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38816, July 25, 2001]

§888.5980 Manual cast application and removal instrument.

(a) *Identification*. A manual cast application and removal instrument is a nonpowered hand-held device intended to be used in applying or removing a cast. This generic type of device includes the cast knife, cast spreader, plaster saw, plaster dispenser, and casting stand.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §888.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180, regarding general requirements concerning records, and §820.198, regarding complaint files.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52954, Dec. 29, 1988; 66 FR 38816, July 25, 2001]

PART 890—PHYSICAL MEDICINE DEVICES

Subpart A—General Provisions

Sec.

890.1 Scope.

890.3 Effective dates of requirement for premarket approval.

890.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Physical Medicine Diagnostic Devices

890.1175 Electrode cable.
890.1225 Chronaximeter.
890.1375 Diagnostic electromyograph.
890.1385 Diagnostic electromyograph needle electrode.
890.1450 Powered reflex hammer.
890.1575 Force-measuring platform.

890.1600 Intermittent pressure measurement system.
890.1615 Miniature pressure transducer.
890.1850 Diagnostic muscle stimulator.
890.1925 Isokinetic testing and evaluation system.

Subpart C [Reserved]

Subpart D—Physical Medicine Prosthetic Devices

890.3025 Prosthetic and orthotic accessory.
890.3075 Cane.
890.3100 Mechanical chair.
890.3110 Electric positioning chair.
890.3150 Crutch.
890.3175 Flotation cushion.
890.3410 External limb orthotic component.
890.3420 External limb prosthetic component.
890.3475 Limb orthosis.
890.3490 Truncal orthosis.
890.3500 External assembled lower limb prosthesis.
890.3520 Plinth.
890.3610 Rigid pneumatic structure orthosis.
890.3640 Arm sling.
890.3665 Congenital hip dislocation abduction splint.
890.3675 Denis Brown splint.
890.3690 Powered wheeled stretcher.
890.3700 Nonpowered communication system.
890.3710 Powered communication system.
890.3725 Powered environmental control system.
890.3750 Mechanical table.
890.3760 Powered table.
890.3790 Cane, crutch, and walker tips and pads.
890.3800 Motorized three-wheeled vehicle.
890.3825 Mechanical walker.
890.3850 Mechanical wheelchair.
890.3860 Powered wheelchair.
890.3880 Special grade wheelchair.
890.3890 Stair-climbing wheelchair.
890.3900 Standup wheelchair.
890.3910 Wheelchair accessory.
890.3920 Wheelchair component.
890.3930 Wheelchair elevator.
890.3940 Wheelchair platform scale.

Subpart E [Reserved]

Subpart F—Physical Medicine Therapeutic Devices

890.5050 Daily activity assist device.
890.5100 Immersion hydrobath.
890.5110 Paraffin bath.
890.5125 Nonpowered sitz bath.
890.5150 Powered patient transport.
890.5160 Air-fluidized bed.
890.5170 Powered flotation therapy bed.
890.5180 Manual patient rotation bed.
890.5225 Powered patient rotation bed.

§ 890.1

21 CFR Ch. I (4–1–05 Edition)

890.5250 Moist steam cabinet.
890.5275 Microwave diathermy.
890.5290 Shortwave diathermy.
890.5300 Ultrasonic diathermy.
890.5350 Exercise component.
890.5360 Measuring exercise equipment.
890.5370 Nonmeasuring exercise equipment.
890.5380 Powered exercise equipment.
890.5410 Powered finger exerciser.
890.5500 Infrared lamp.
890.5525 Iontophoresis device.
890.5575 Powered external limb overload warning device.
890.5650 Powered inflatable tube massager.
890.5660 Therapeutic massager.
890.5700 Cold pack.
890.5710 Hot or cold disposable pack.
890.5720 Water circulating hot or cold pack.
890.5730 Moist heat pack.
890.5740 Powered heating pad.
890.5765 Pressure-applying device.
890.5850 Powered muscle stimulator.
890.5860 Ultrasound and muscle stimulator.
890.5880 Multi-function physical therapy table.
890.5900 Powered traction equipment.
890.5925 Traction accessory.
890.5940 Chilling unit.
890.5950 Powered heating unit.
890.5975 Therapeutic vibrator.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 48 FR 53047, Nov. 23, 1983, unless otherwise noted.

Subpart A—General Provisions

§ 890.1 Scope.

(a) This part sets forth the classification of physical medicine devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a physical medicine device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[52 FR 17741, May 11, 1987]

§ 890.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application of premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28,